K023289



# 510(k) Summary (Section 9)

JAN 1 5 2003

# Summary of Safety and Effectiveness

## Applicants Name and Address

Dräger Medical AG & Co. KGaA
Moislinger Allee 53-55
D-23542 Lübeck
Germany

## Applicants Contact Person

Mr. Ulrich Schröder
Manager Regulatory Affairs

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Fax No.: 011 49 (451) 882-4351

## Applicants US Contact Person

Mr James J. Brennan
Director Regulatory Affairs

Tel. No.: (215) 721-5400
Fax No.: (215) 721-5412

## Date the Summary was prepared

September 27, 2002

## Device Name

| | |
|---|---|
| Trade Name: | NIV Option |
| Common Name: | **NIV Option for Dräger Intensive Care Ventilator Savina** |
| Classification Name: | Ventilator, Continuous (per 21 CFR 868.5895) |

## Legally marketed device to which Substantial Equivalence is claimed

Evita 4 / Evita 2 dura with option NIV (K010093)
Manufactured by Dräger Medical AG & Co. KGaA Germany.
Manufactured and Distributed in the United States by Dräger Medical Inc.

Savina (K003068)
Manufactured by Dräger Medical AG & Co. KGaA; Germany.
Distributed in the United States by Dräger Medical Inc.

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## Description of the Device

Savina is a long term ventilator unit designed for patients with a tidal volume of 50 ml or more and is used in the intensive care areas, recovery rooms, inter and intra hospital transport and subacute care facilities. NIV means *Non-Invasive Ventilation* and supports the mask application mode. The NIV Option is available for Savina with SW 2.0.

The NIV Option for Savina expands the range of available ventilation strategies to include Non-Invasive Ventilation. NIV is not a new ventilation mode but a different format to deliver ventilation to the patient. With the NIV Option activated, the user can switch the ventilator during preparation of the machine into one of two application modes: a) "Tube" application mode, b) "Mask" application mode. The "Tube" application mode corresponds to the regular behavior of the device if the NIV option is not activated.

If the "Mask" application mode is selected, the user gains the option to configure parts of the device integrated monitoring to adapt the specific need of the mask ventilated patient.

## Intended Use

Long-term Ventilator for intensive care. For patient requiring tidal volume starting at 50 ml.

## Substantial Equivalence

The intended use of Savina SW 2.n with NIV Option is covered by the referenced predicate devices

Savina SW 1.n
Evita 4 and Evita 2 dura SW 4.n with NIV

The technical characteristics of the NIV option do not raise new questions regarding safety or effectiveness. Furthermore the labelling of Savina SW 2.n with NIV provides similar information as the predicate devices.

Information provided in the 510(k) Premarket Notification supports the determination of substantial equivalence. Design, development and verification of the device was performed in accordance with FDA guidance and company internal standards. The testing and analysis of results provide assurance that the device meets its specifications and is safe and effective for its intended use.

In summary Dräger Medical AG & Co. KGaA has demonstrated that Savina SW 2.n including the NIV option to be safe and effective. Savina SW 2.n with NIV is considered to be substantial equivalent to currently marketed predicate devices which have been previously cleared by FDA.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 5 2003

Dräger Medical AG & Company KGaA
C/O Mr. James J. Brennan
Director, Regulatory Affairs
Drager Medical Incorporated
3135 Quarry Road
Telford, Pennsylvania 18969

Re: K023289
Trade/Device Name: Savina
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: December 12, 2002
Received: December 16, 2002

Dear Mr. Brennan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

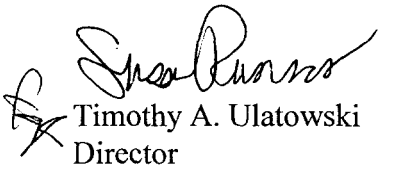
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023289

Device Name: Savina

Indications For Use:

**Long-term ventilator for intensive care. For patient requiring tidal volume starting at 50 ml.**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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